NOV - 9 2009

5. 510(k) Summary

U&I CORPORATION

Manufacturer: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050
Sung-Youn Cho, Regulatory Affairs Manager

Sponsor: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

Sponsor Contact : Sung-Youn Cho, Regulatory Affairs Manager

Date Prepared: June 4, 2009

Device Name: Trade Name: *Perfix*™ Spinal System

Common Name: Spinal Fixation System

Classification Name: Orthosis, Spondylolisthesis Spinal Fixation (MNH), per 21 CFR 888.3070

Orthosis, Spinal Pedicle Fixation (MNI), per 21 CFR 888.3070

Spinal Interlaminal Fixation Fixation Orthosis (KWP), per 21 CFR 888.3050

Product Code: MNH, MNI, KWP

Predicate Devices: *OPTIMA*™ Spinal System (K024096)

Description of Device:

The *Perfix*™ Spinal System is manufactured by U&I corporation. The *Perfix*™ is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism. The *Perfix*™ Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The *Perfix*™ implant system components are supplied non-sterile, single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136.

Intended Use:

The *Perfix™* Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Substantial Equivalence:

The *Perfix™* Spinal System is substantially equivalent to the pedicle screws of the *OPTIMA™* Spinal System in design, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

U & I Corporation
% Sung-Youn Cho
Regulatory Affairs Manager
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

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Re: K091725
Trade/Device Name: Perfix™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: September 23, 2009
Received: September 25, 2009

Dear Sung-Youn Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

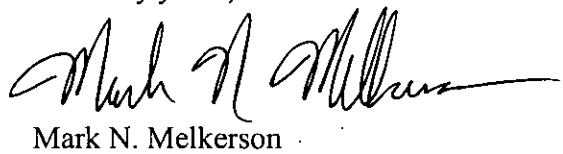
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091725

Device Name: *Perfix*™ Spinal System

Indications for Use:

The *Perfix*™ Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

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- Tumor
- Pseudoarthrosis
- Failed previous fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices